UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE WELLBUTRIN SR/ZYBAN ANTITRUST LITIGATION	Master File No. 02-CV-4398
THIS DOCUMENT RELATES TO:	Judge Bruce W. Kauffman
ALL ACTIONS	

DEFENDANTS' SUPPLEMENTAL MEMORANDUM IN SUPPORT OF MOTION TO DISMISS

Mark S. Stewart
Leslie E. John
Ballard Spahr Andrews & Ingersoll, LLP
1735 Market Street, 51st Floor
Philadelphia, PA 19103
(215) 864-8225

William J. Baer
Kenneth A. Letzler
Cathy Hoffman
Amy Ralph Mudge
June Im
H. Holden Brooks
Arnold & Porter
555 12th St., NW
Washington, DC 20004
(202) 942-5000

Timothy A. Thelen
Assistant General Counsel
GlaxoSmithKline
Five Moore Drive
Research Triangle Park, NC 27709
(919) 483-1480

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

MISCELLANEOUS

Defendants have moved to dismiss this action because the theory of antitrust causation alleged in the Complaint is untenable as a matter of law. The conclusory allegation of causation in the Complaint cannot be established by any set of facts alleged in the Complaint nor by any set of facts consistent with the allegations of the Complaint. In this Supplemental Memorandum, we address the following issues arising out of oral argument:

First, as the Court requested, we address the propriety of taking judicial notice of the fact, which Plaintiffs admit, that Andrx, the first filer of an Abbreviated New Drug Application ("ANDA") for sustained release generic bupropion hydrochloride, still has not received Food and Drug Administration ("FDA") approval to market its generic drug.

Second, we address the Plaintiffs' new, unpled theory of "what this case fundamentally is about," and the six new, unpled causation "scenarios" that flow from that theory. (Apr. 14, 2003 Transcript ("Tr.") at 42.) At oral argument Plaintiffs retreated from the Complaint's critical allegations that Defendants' patent infringement lawsuits were objectively baseless. Instead, Plaintiffs now say that the patent suits raised "very complicated, very difficult questions of patent law as an obstacle between the entry of the generics and actually the potential for getting to market." (Id. at 42-43 (emphasis added).) Based on this new theory, they posit six "causation" scenarios — speculative chains of events that "it's not wild to suggest" could have occurred. (Id. at 60.) But Plaintiffs' new theory and their resulting causation "scenarios" cannot save their Complaint for three reasons:

- The theory and scenarios are inconsistent with the Complaint's critical allegations that Defendants' patent suits were "objectively baseless."

- The theory and scenarios do not reflect antitrust injury that flows from the conduct alleged in the Complaint to have been unlawful, as required by City of Pittsburgh v. West Penn Power Co., 147 F.3d 256 (3d Cir. 1998).

- The theory and scenarios do not cure the failure to plead facts supporting causation other than the now discredited (and abandoned) automatic thirty-month stay theory.

Finally, we address the question the Court raised at argument whether the generic companies that filed ANDAs are "indispensable parties" to this litigation. We conclude that they are not.

I. THE COURT CAN AND SHOULD TAKE JUDICIAL NOTICE OF AN ADMITTED FACT THAT APPEARS IN PUBLIC RECORDS OF THE FOOD AND DRUG ADMINISTRATION

We have asked the Court to take judicial notice of the fact that Andrx has not received FDA approval of its ANDA, despite the passage of fifteen months since expiration of the automatic thirty-month stay. Under Pension Benefit Guar. Corp. v. White Consol. Indus., Inc., 998 F.2d 1192 (3d Cir. 1993), a court considering a motion to dismiss may take judicial notice of "published reports of administrative bodies." Id. at 1197. We have provided the Court with a published report from the official website of a federal administrative agency, the FDA, which makes plain that Andrx has not received FDA approval.[1]

Plaintiffs concede that Andrx has not obtained tentative or final FDA approval.[2] Plaintiffs also concede that the cited FDA website is a "report" that is "publicly

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[1] Def. Mem. in Supp. of Mot. to Dismiss ("Def. Mem.") at 5 & Ex. 1, citing the FDA's Center for Drug Evaluation and Research Listing of New & Generic Drug Approvals ("FDA Drug Products Approvals List") found on the FDA's website. See http://www.fda.gov/cder/approval/b.htm (last visited on May 5, 2003) (attached as Ex. 1).

[2] The End Payor Pls.' Opp'n to Defs.' Mot. to Dismiss ("Opp'n") at 5 ("Andrx, the first ANDA filer for Wellbutrin SR and Zyban, notified Defendants of its application in

[Footnote is continued on next page]

available." (The End Payor Pls.' Opp'n to Defs.' Mot. to Dismiss ("Opp'n") at 11.) Plaintiffs have nevertheless suggested that judicial notice might be improper.

In their brief, Plaintiffs argued that judicial notice is improper because the records on which the FDA report is based are not publicly available. (Opp'n at 11-12.) But Pension Benefit contains no such requirement; it is enough that the report itself is public. See 998 F.2d at 1197.

At oral argument, the Court asked what the cases say about taking judicial notice of records on agency websites. (Tr. at 28.) Plaintiffs suggested that a website report might be more informal or inaccurate than a "hard copy" report. (Id. at 29-30.) In fact, however, numerous courts, including a court in this district, have taken judicial notice of agency website reports. See McLaughlin v. Volkswagen of Am., Inc., No. CIV. A. 00-3295, 2000 WL 1793071, at *1 (E.D. Pa. Dec. 6, 2000) (taking judicial notice, in ruling on motion to dismiss, of National Highway Traffic Safety Administration's website description of vehicle recall).[3]

[Footnote continued from previous page]

August of 1999, but has yet to receive FDA approval."); Apr. 14, 2003 Transcript ("Tr.") at 23-24 (The Court: "Are you saying that . . . Andrx . . . failed to receive approval of their abbreviated applications, even up to now, even though 30 months has run more than a year ago. . . . [D]o the plaintiffs dispute that[?]" Mr. Richards: "[W]e don't dispute the fact. . . ."). Plaintiffs' concessions that Andrx does not have FDA approval are judicial admissions that can be considered in ruling on a motion to dismiss. See Conte Bros. Auto., Inc. v. Quaker State-Slick 50, Inc., 165 F.3d 221, 235-36 (3d Cir. 1998) (upholding district court's reliance in dismissing complaint on plaintiffs' concessions in its brief and during argument).

[3] See Ligon v. Doherty, 208 F. Supp. 2d 384, 386 (E.D.N.Y. 2002) (taking judicial notice of New York State Prisons website identifying inmate locations); In re Agribiotech Sec. Litig., CV-S-990144 PMP (LRL), 2000 U.S. Dist. LEXIS 5643, at *4-5 (D. Nev. Mar. 2, 2000) ("In this new technological age, official government ... documents may be judicially noticed insofar as they are available via the world wide web."); Modesto Irrigation Dist. v. Pacific Gas & Elec. Co., 61 F. Supp. 2d 1058, 1066 (N.D. Cal. 1999)

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Nevertheless, to avoid any question, we are submitting relevant excerpts from a "hard copy" public FDA report that also reflects that Andrx has failed to get FDA approval. FDA publishes a report entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," known as the "Orange Book." The Orange Book lists all brand and generic pharmaceuticals that have received final FDA approval. The Orange Book makes clear that Andrx has not received approval to market a generic bupropion hydrochloride product. See FDA, 2003 Orange Book 3-53, Prescription Drug Product List (no listing of Andrx as approved under extended release bupropion hydrochloride); FDA, February 2003 Orange Book Cumulative Supplement 1-2, Rx Drug Product List (no new listings for bupropion hydrochloride) (attached as Exs. 2-3).[4] It is therefore proper for this Court to take judicial notice of that fact.

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(holding that documents submitted to government agency that are readily accessible through the Internet are judicially noticeable), rev'd on other grounds by N. 99-17069, 2002 WL 31748609 (9th Cir. Dec. 6, 2002).

[4] The full text of the Orange Book is available on the Internet at http://www.fda.gov/cder/orange/adp.htm. The Orange Book monthly supplement is available at http://www.fda.gov/cder/orange/supplement/cspreface.htm. The website report submitted with Defendants' opening brief (see supra note 1) lists tentative as well as final approvals. 2003 Orange Book, Introduction, vii ("Prior to the effective date, [FDA] will not include drug products with tentative approval in the [Orange Book]; however, they are available in the FDA Drug Products Approvals List on the Internet World Wide Web.").

II. PLAINTIFFS' UNPLED CAUSATION "SCENARIOS" ARE INCONSISTENT WITH THE COMPLAINT AND CONTRARY TO GOVERNING THIRD CIRCUIT AUTHORITY

Basic pleading principles, along with the Third Circuit's ruling in City of Pittsburgh v. West Penn Power Co., 147 F.3d 256 (3d Cir. 1998), dictate dismissal of the Complaint.

A. Plaintiffs' Causation Theory Does Not Satisfy Basic Pleading Principles

Two pleading principles govern resolution of this motion. First, factual allegations made only in briefs or at oral argument are not to be considered in ruling on a motion to dismiss. Forrest v. Beloit Corp., No. CIV. A. 00-CV-5032, 2001 WL 1251460, at *2 (E.D. Pa. Sept. 21, 2001) (Kauffman, J.) (citing In re Warfarin Sodium Antitrust Litig., 214 F.3d 395, 398 (3d Cir. 2000)). Second, "[t]he Court may dismiss the complaint only if 'it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations.'" Id. (emphasis added) (quoting H.J. Inc. v. Northwestern Bell Tel. Co., 492 U.S. 229, 249-50 (1989) (quoting Hishon v. King & Spaulding, 467 U.S. 69, 73 (1984))).

Plaintiffs' arguments run afoul of these principles. The theories and speculations they put forward at argument (and not in their Complaint) are inconsistent with the crucial allegations of the Complaint.

1. Plaintiffs' New Unpled Theory of "What This Case Fundamentally Is About" Is Inconsistent with the Complaint

A party trying to allege a viable antitrust causation theory based on the allegedly unlawful filing of litigation is walking a tightrope. To avoid the law that the filing of litigation is "generally immune from antitrust liability" that party must allege, as

Plaintiffs have here, that the challenged litigation was "objectively baseless,"[5] i.e., so frivolous "that no reasonable litigant could realistically expect success on the merits. If an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome, the suit is immunized under Noerr, and an antitrust claim premised on the sham exception must fail." Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 56, 60 (1993).[6] The allegation that a lawsuit was objectively baseless leaves Plaintiffs with a dilemma when it comes to pleading causation: How can a frivolous lawsuit have caused any real-world effect, given that no reasonable litigant would, by definition, think that the lawsuit had a chance to succeed?

The conventional way to deal with the tension between the need to claim that the challenged lawsuit is frivolous and the need to assert a plausible causation theory — and the way chosen in the Complaint here — is to allege that the case was objectively baseless and to omit any allegation that a generic firm would treat it seriously, but to assert that injury nonetheless occurred because even a frivolous lawsuit triggers a statutory mechanism that deprives FDA of the power to make its approval of an ANDA effective for a thirty-month period.[7] Thus, the Complaint alleges that Defendants brought

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[5] See, e.g., Compl. ¶ 6 ("Defendants have instituted a series of patent infringement actions . . . which are objectively baseless and without merit. . . .").

[6] See Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127 (1961); United Mine Workers of Am. v. Pennington, 381 U.S. 657 (1965).

[7] In antitrust claims brought by generic companies themselves to challenge the filing of sham patent litigation, some courts have found the claimed injury to include the cost of defending the baseless suit, which is caused directly by the filing of the litigation. The case on which Plaintiffs principally rely, Bristol-Myers Squibb Co. v. Ben Venue Labs., 90 F. Supp. 2d 540 (D.N.J. 2000), is such a case. Plaintiffs here, of course, cannot assert that injury because they did not bear that cost.

baseless litigation, not with any hope of winning the cases, but "for the purpose of triggering the 30-month stay." (Compl. ¶ 6.) "This extension of market exclusivity," i.e., the time during which FDA was prevented from making approval effective, is alleged to have injured Plaintiffs. (Id. (emphasis added).)[8] The Complaint repeatedly suggests that absent the litigations, "generic versions of Wellbutrin SR . . . could have been available as early as September 15, 1999" through approval of the Andrx ANDA. (E.g., Compl. ¶ 1.)[9]

There may be cases in which a generic applicant obtains prompt tentative approval of an ANDA from FDA but has to wait to sell the product until the thirty-month stay has expired. The entire theory of the Complaint here mirrors that theory. It is dependent upon the first ANDA filer getting tentative approval quickly, e.g., by September 1999, but not being able to get final approval because of the thirty-month stay. But that simply did not happen here. As Plaintiffs concede, a year and a quarter has passed since the thirty-month stay against FDA final approval of Andrx's ANDA expired, and Andrx still has not received approval.

Because Plaintiffs have no answer to the fact that the causation alleged in the Complaint did not occur, they have shifted grounds entirely. At argument Plaintiffs posited "various alternative scenarios" of causation, none of which was pled in the

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[8] See also Compl. ¶¶ 91 (bringing objectively baseless litigation "for the purpose of triggering the 30-month stay"); 161 (bringing baseless litigation "in order to prevent FDA from granting final approval").

[9] As alleged in the Complaint, the other generic companies filed months or years after Andrx (Compl. ¶¶ 80, 84, 86, 115) and only Andrx had an application on file that the FDA could approve as of September 15, 1999. (Compl. ¶ 75.)

Complaint. (Tr. at 69.) Each of these scenarios rests on a theory of "what this case fundamentally is about," (Id. at 42), that is inconsistent with the Complaint's allegations that Defendants' lawsuits were frivolous. Instead, Plaintiffs now assert that Defendants' lawsuits raised "very complicated, very difficult questions of patent law as an obstacle between the entry of the generics and actually the potential for getting to market." (Id. at 42-43 (emphasis added).)[10]

If this new premise is correct, however, then Defendants' patent suits were not objectively baseless. They were, rather, genuine petitioning activity that is immune from antitrust liability. Thus, the theory of "what this case fundamentally is about" that Plaintiffs now embrace to support causation is inconsistent with what Plaintiffs had to allege to avoid Noerr immunity.

2. The Six "Scenarios" Are Inconsistent with the Complaint

Each of the new scenarios rests on a world in which the patent suits were not frivolous, but, rather, were perceived as being so threatening that the generics and the FDA changed their behavior substantially enough to delay generic entry. For convenience, we quote below the six scenarios that Plaintiffs' counsel described at argument:

> The "Andrx/GlaxoSmithKline Conspiracy" Scenario:
> "Andrx could have conspired with the defendants to slow

[10] See also Tr. at 43 (stating that generic companies are "in a materially different position, having been sued, and having to overcome this patent litigation in order to get to market"); id. at 44 ("[T]hat different position is likely to affect [generic company] behavior in all kinds of areas, including [] efforts to get approval to bring [the] drug to market."); id. at 51 (alleging that "lawsuits had the consequence of keeping enormous hurdles in the face of the would be generic entrants").

> down, frustrate, hinder, not pursue, whatever, its own approval." (Tr. at 60.)
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> The "Andrx Slowed Down" Scenario: "Were it not for the suit against Andrx, Andrx would have been much more motivated to pursue approval." (Tr. at 56.)
>
> The "Other Generics Slowed Down But Could Have Teamed Up With Andrx" Scenario: "Were it not for the lawsuits against them, some of the other generics, Impa[x], Excel, likewise would have been more motivated to obtain approval. And then if they got approval, they could have combined their approval just like Eon could, with Andrx first place in line, and come to market with a generic." (Tr. at 56.)
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> The "Eon Could Have Teamed Up with Andrx" Scenario: "Eon, had it not been sued in this frivolous lawsuit, could have taken its approval, it could have coupled that with Andrx with their first place in line, and they might have been able to come to market with a generic drug and make a lot of money together." (Tr. at 55.)
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> The "Watson Backed Off and Failed to Team up with Andrx" Scenario: "[I]f Watson had not been baselessly sued in December of '99, Watson might have obtained approval were it not for a potential agreement with the defendants, you know, to — to back off as it were. And Watson could then, if it got approval, have teamed up with Andrx in order to bring a generic to market." (Tr. at 49.)
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> The "FDA Could Have Taken Different Actions" Scenario: The lawsuits were "likely to affect the alacrity with which the FDA pushes for the approval." (Tr. at 54.) "[T]he FDA could disapprove Andrx filing. And that would free the FDA up to let one of the other generics go forward." (Tr. at 64.)

Under these scenarios, no longer is it the case, as alleged in the Complaint, that a reasonable litigant like Andrx would have recognized that it was going to win the patent suit and would have been prepared to start marketing the product on September 15, 1999,

shortly after it submitted its FDA application.[11] Instead, Plaintiffs now say their very same Complaint should be read to allege that the lawsuits were sufficiently daunting that they may have caused the generics (other than Eon)[12] to slow down their ANDA approval efforts, caused Watson to "back off" its ANDA entirely, and caused FDA to slow down processing all of the ANDAs (except Eon's). Moreover, Plaintiffs say that absent the serious threat posed by the lawsuit, Andrx might have realized sooner that it could not get FDA approval as of September 15, 1999 (as the Complaint so clearly states) and thrown in the towel on its own FDA application to enter into a "teaming up" arrangement with Eon, Watson, Impax, or Excel.[13]

None of these scenarios can be squared with the Complaint's allegations that the lawsuits were objectively baseless. Objectively baseless lawsuits would not cause generics to "back off," slow down, and throw in the towel on their attempts to get FDA approval either unilaterally or by unlawful conspiracy with GlaxoSmithKline ("GSK"). Only lawsuits that had a reasonable chance of succeeding might put in motion those speculative chains of events. Bringing legitimate cases that present complex legal issues is not an antitrust violation. But Plaintiffs' new theory of causation — an "avalanche of causal results" (Tr. at 51) flowing from "very complicated, very difficult" (Tr. at 42) litigation — makes sense only on the assumption that Defendants' patent suits were legitimate and presented complex legal issues.

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[11] Allegations of a September 1999 entry date are pervasive. (See, e.g., Compl. ¶¶ 1, 4, 24, 118.)

[12] As alleged in the Complaint, ¶ 83, Eon has obtained tentative FDA approval.

[13] See infra note 16 and accompanying text.

Beyond this fundamental inconsistency between the Complaint and the unalleged scenarios, other inconsistencies and legal flaws abound:

- The Complaint alleges that Andrx is a victim of Defendants' unilateral unlawful behavior, not a willing participant in an altogether different kind of unlawful behavior, a conspiracy;[14]

- An ANDA first filer that fails to pursue its FDA application actively could be stripped of its valuable exclusivity rights. See 21 C.F.R. § 314.107(c)(3) (2003). The speculation that Andrx would slow down its application and run this risk cannot be squared with the Complaint's allegation that the patent suit against Andrx was so frivolous that no reasonable litigant could have expected Andrx to lose.[15]

- The scenarios under which Watson, Eon, Impax, and Excel could have "teamed up" with Andrx reflect a fundamental misunderstanding of FDA law. Plaintiffs' suggestion that Andrx could have transferred its first-filer exclusivity rights to one of the other generics is incorrect. FDA prohibits the assignment or sale of first filer exclusivity rights to a particular generic, cf. 59 Fed. Reg. 50,338 at 50,359 (Oct. 3, 1994), and does not allow any selective waiver of such rights unless and until the exclusivity period has been triggered.[16] Since Andrx's exclusivity period has still not

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[14] Plaintiffs say that they did not give notice of a GSK-Andrx conspiracy in their Complaint because, despite describing it in their Opposition as a per se violation of the Sherman Act § 1 if proven (Opp'n at 3), they are not alleging conspiracy as a substantive violation of law but simply as a "causation element" of Plaintiffs' injury arising from a § 2 monopolization violation. (Tr. at 74.) Defendants are not aware of any cases that support such a notion.

[15] Conclusory allegations of causation cannot be defended on a motion to dismiss by conjuring up implausible scenarios directly at odds with the theory and allegations of the Complaint. See Brunson Communications, Inc. v. Arbitron, Inc., 239 F. Supp. 2d 550, 563-4 n.5 (E.D. Pa. 2002) (finding that where "the conspiracy theorized by [p]laintiff is . . . economically implausible," dismissal is proper) (citing, inter alia, DM Research, Inc. v. Coll. of Am. Pathologists, 170 F.3d 53, 56 (1st Cir.1999)). Like the Queen of Hearts, Plaintiffs have "believed as many as six impossible things before breakfast." Lewis Carroll, Through the Looking Glass, available at http://www.literature.org/authors/carroll-lewis/through-the-looking-glass/chapter-05.html. Defendants, however, have "embrace[d] the [C]omplaint" for purposes of this Motion (Tr. at 77), and Plaintiffs must do the same.

[16] FDA explained this policy in the preamble to a proposed rule on 180-day exclusivity. 64 Fed. Reg. 42,873, 42,881 (Aug. 6, 1999). Although FDA withdrew the proposed rule, 67 Fed. Reg. 66,593 (Nov. 1, 2002), its statements prohibiting selective waiver prior to triggering of the 180-day period reflect policy that the agency has in fact implemented, rather than simply being a proposal.

been triggered, Andrx could not have waived its exclusivity rights in favor of Watson, Eon, Impax, or Excel specifically. It could only waive the 180-day period entirely, giving up a right that the Complaint recognizes is highly lucrative (Compl. ¶ 40).

- The speculation that FDA slowed down because of the pendency of the lawsuits is inconsistent with the Complaint's allegation that FDA long ago gave tentative approval to the ANDA of Eon, the fourth generic filer, despite the pendency of a patent suit. (Compl. ¶ 83.) The speculation is also incorrect as matter of law. The Hatch-Waxman Act indicates that FDA should process ANDAs regardless of the pendency of the thirty-month stay. See 21 U.S.C. § 355(j)(5)(B)(iii) (2000); 21 C.F.R § 314.107(b) (2003). FDA's formal policies give it no latitude to delay processing of ANDAs because of the pendency of patent litigation and the resulting thirty-month stay.[17] And the courts have recognized that the thirty-month stay does not delay FDA's processing of ANDAs. See Bristol-Myers Squibb Co. v. Copley, 144 F. Supp. 2d 21, 23 (D. Mass. 2000) (rejecting litigant's contention that a patent suit slows down the FDA's ANDA approval process); Ben Venue Labs., Inc. v. Novartis Pharm. Corp., 10 F. Supp. 2d 446, 458 (D.N.J. 1998) (finding that the thirty-month stay does not apply to FDA review process).

B. City of Pittsburgh v. West Penn Power Co. Requires Dismissal

City of Pittsburgh v. West Penn Power Co., 147 F.3d 256 (3d Cir. 1998), cited in Defendants' opening brief, independently requires dismissal. In West Penn, the City of Pittsburgh alleged that a proposed merger of two power companies, Allegheny and Duquesne, and Allegheny's premerger agreement with Duquesne to withdraw its application with the Public Utility Commission ("PUC") for approval to provide electric service, would violate the antitrust laws. The Third Circuit affirmed the district court's 12(b)(6) dismissal of the action on the ground that there was a lack of causal connection

[17] FDA operates according to a "first-in first-reviewed" policy for ANDAs. See Center for Drug Evaluation and Research's Manual of Policies and Procedures ("MAPP"), section 5240.3. (Attached as Ex. 4.) This policy states that ANDAs will be "initiated and pursued . . . in the order in which they are received by the Office [of Generic Drugs]. . . ." The policy allows no latitude for treating ANDAs differently where a patent suit has been filed.

between the defendants' actions and the alleged harm and because of the absence of antitrust injury. Id. at 265.

As is the case here, the claims in West Penn were made against the backdrop of a regulated industry. A utility company can sell power only if it has obtained a certificate of public convenience from the PUC. Id. at 259. Duquesne was the only utility with the requisite approval. Id. at 260. Allegheny had applied for PUC approval, but the PUC had not ruled by the time Allegheny and Duquesne entered into their agreement and Allegheny withdrew its application. Id. at 261-62.

The Third Circuit indicated that the question on the motion to dismiss was whether the alleged injury flowed "'from that which makes the defined acts unlawful.'" Id. at 265 (internal citations omitted). "To answer this question," the court continued, "we must examine the causal connection between the purportedly unlawful conduct and the injury." Id. This test directs the court "to look back from the vantagepoint of the injury to test the nature of the cause, rather than to presume antitrust injury wherever there is an agreement or merger that results in harm." Id. at 266.

Based on these principles, the court found that the requisite causal connection between the challenged conduct and the alleged injury was missing:

> The purported lessening of competition was not caused by the premerger agreement and proposed merger between Allegheny Power and Duquesne Light. The City's inability to choose to buy from either Allegheny Power or Duquesne Light for the Redevelopment Zones is an injury visited upon it by the regulated nature of utility services, not caused by an agreement between Duquesne Light and Allegheny Power to withdraw Allegheny Power's application to be able to compete.

Id. at 266. The court went on to say:

> Allegheny Power was not legally able to provide power in the Redevelopment Zones and we do not know whether the PUC would ever have granted the permission for it to do so. Thus, as a matter of law, the court cannot conclude that the loss of potential competition was causally related to the decision of the two power companies to merge. The City is really claiming that it would have benefitted from competition it hoped would occur. However, the appellants cannot foist their version of what might have been on the court under the rubric of antitrust injury. The presence of the regulatory scheme and need for approval in connection with the choice of utilities to serve the Redevelopment Zones cuts the causal chain and converts what might have been deemed antitrust injury in a free market into only a speculative exercise.
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> . . . .
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> [W]e simply cannot know whether there is any causal connection between the harm which has arguably been suffered by the City and the alleged Sherman Act violation.
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> . . . .
>
> The statutory scheme precluded competition without the requisite regulatory permission. As Professors Areeda & Hovenkamp describe, "a plaintiff cannot be injured in fact by private conduct excluding him from the market when a statute prevents him from entering that market in any event."

Id. at 267-68 (quoting Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law ¶ 363(b), at 222 (1995) (internal citations omitted)).

West Penn demonstrates that the theory alleged in Plaintiffs' Complaint here — that Defendants filed frivolous lawsuits for the purpose of triggering the automatic thirty-month stay — is untenable as a matter of law, when the thirty-month stay expired more than a year ago and the first filer still has not received regulatory approval to sell its product. Thus, Plaintiffs cannot show, just as the City of Pittsburgh could not show in

opposing a motion to dismiss, that absent the conduct challenged in the Complaint, there would be competitors on the market.

West Penn also demonstrates why the new theories that Plaintiffs pronounced at oral argument are untenable. West Penn teaches that in an antitrust case, the alleged injury must "'flow[] from that which makes defendants' acts unlawful.'" Id. at 265 (citing Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc., 429 U.S. 477, 489 (1977)). The Complaint here alleges that what makes Defendants' acts unlawful is the objectively baseless nature of Defendants' patent suits. But what Plaintiffs' speculations now rest on is that the lawsuits were not frivolous, but instead were viewed as presenting "very complicated, very difficult questions" that raised "enormous hurdles." (See supra note 10.)

Plaintiffs' new theories thus in fact do not make a causal link between the conduct challenged in the Complaint (frivolous lawsuits) and the alleged injury (lack of generic competitors). Instead, these new theories raise unpled factual allegations as to what type of conduct caused the alleged injury. An allegation that Defendants violated the antitrust laws by conspiring with Andrx or Watson to prevent or delay generic entry and that, as a result, there has been no generic entry could well satisfy the causation pleading requirement. But there is no such allegation in the Complaint, and any such allegation would contradict the entire theory of Plaintiffs' Complaint.

Under Plaintiffs' new scenarios, they may have indeed been "injured" by the lawsuits, but in the same way they would have been injured if Defendants won all the patent suits and succeeded in keeping the generics out through successful litigation. Just as the antitrust laws do not offer redress to someone who has been unable to purchase a

generic product because the generic product infringes a valid patent, they likewise do not offer redress to someone who was unable to purchase a generic product because the generics delayed their efforts at entry in the face of objectively reasonable patent infringement litigation. Either the lawsuits were objectively baseless, as alleged in the Complaint, or they were not, as posited by the contradictory new scenarios. But only in a world where the suits were objectively baseless do these Plaintiffs have the ability to seek redress under the antitrust laws. A chain of events that allegedly resulted from the filing of constitutionally protected lawsuits does not, as a matter of law, give rise to an actionable antitrust injury.

C. Plaintiffs Cannot Rely on Conclusory Allegations of Evil Intent and Causation

Plaintiffs suggested four "legal reasons" why their Complaint should survive. (Tr. at 69-94.) These all boil down to a suggestion that the Complaint passes muster because it paints a picture of Defendants' evil intent and contains conclusory allegations that Defendants' conduct caused Plaintiffs' injury. (Tr. at 69-70.) In other words, Plaintiffs are saying that, because we have to assume the Complaint's allegations are true, we know Defendants' intent was bad, and combined with the Complaint's conclusory assertions of causation, that is good enough to warrant letting Plaintiffs find out through discovery exactly what Defendants did that was unlawful.

Under the law of this Circuit and the Supreme Court, it is not good enough. Antitrust complaints routinely contain boilerplate assertions that the defendant's conduct caused the plaintiff's injury, but the Third Circuit has repeatedly upheld dismissals of antitrust complaints on causation grounds. See Allegheny Gen. Hosp. v. Philip Morris,

Inc., 228 F.3d 429, 443 (3d Cir. 2000); Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris, Inc., 171 F.3d 912, 928 (3d Cir. 1999); West Penn Power Co., 147 F.3d at 265. Conclusory allegations cannot be credited in ruling on a motion to dismiss. See In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1429-30 (3d Cir. 1997) (finding that a court "need not credit a complaint's bald assertions or legal conclusions" when deciding a motion to dismiss) (internal quotations and citation omitted); Brunson Communications, Inc. v. Arbitron, Inc., 239 F. Supp. 2d 550, 568 (E.D. Pa. 2002) (citing Pao v. Holy Redeemer Hosp., 547 F. Supp. 484, 491 (E.D. Pa. 1982)); Rototherm Corp. v. Penn Linen & Uniform Serv., Inc., No. Civ. A. 96-6544, 1997 WL 419627 at *17 (E.D. Pa. July 3, 1997).

Combining those conclusory assertions with allegations of the Defendants' bad intent is also not good enough, because allegations of evil purpose are not "a panacea that will enable any complaint to withstand a motion to dismiss." Associated Gen. Contractors of Cal. v. Cal. State Council of Carpenters, 459 U.S. 519, 537 (1983).[18] To state a monopolization claim under Section 1 of the Sherman Act, Plaintiffs must allege what conduct violated the law and how that conduct injured them. (See Def. Reply Mem. in Supp. of Mot. to Dismiss at 6-7.) Plaintiffs' Complaint identified the unlawful conduct: objectively baseless lawsuits. Plaintiffs' Complaint also identified how that conduct allegedly injured them: by triggering a thirty-month stay to which Defendants

[18] See Allegheny Gen. Hosp. v. Philip Morris, Inc., 228 F.3d 429, 439 (3d Cir. 2000) (finding that an "invocation of specific intent to harm does not automatically create standing"); Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris, Inc., 171 F.3d 912, 925 (3d Cir. 1999); Merican, Inc. v. Caterpillar Tractor Co., 713 F.2d 958, 964 (3d Cir. 1983); Midland Export, Ltd. v. Elkem Holding, Inc., 947 F. Supp. 163, 166 (E.D. Pa. 1996).

were not entitled because their lawsuits were objectively baseless. But as it turns out, this theory is untenable because the thirty-month stay has not delayed FDA approval.

Plaintiffs respond by concocting six new causation "scenarios," all of which are based on conduct — the filing of complicated, difficult lawsuits, and not objectively baseless lawsuits — that is not actionable under the antitrust laws. Plaintiffs' attempts to remedy the deficient causation element of their cause of action thus result in them creating a deficient conduct element of their cause of action. Defendants are not asking this Court, as Plaintiffs would have it, to apply a "heightened" pleading standard to their Complaint, nor are Defendants seeking anything other than a "short and plain statement" of the claim. Defendants are asking this Court to apply normal pleading standards, which require the Complaint to identify the conduct that allegedly injured Plaintiffs and the way in which it injured them. Plaintiffs can and do say over and over that Defendants had evil motives, but those repeated incantations do not justify letting this otherwise deficient Complaint go forward.

For the reasons stated above, Plaintiffs' Complaint should be dismissed. If, however, the Court is inclined to let Plaintiffs take discovery to determine if there is any basis for their speculations, we respectfully submit that the Court should limit discovery to two issues that we believe can and should be resolved quickly through a motion for summary judgment: (1) whether Defendants' patent suits against the generics were "objectively baseless" and (2) whether the lawsuits caused the lack of generic entry.[19]

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[19] "Merits" document discovery has commenced pursuant to an Order of Magistrate Angell dated February 28, 2003 to conclude by the end of July 2003. Plaintiffs have served a document request that is substantially similar to the draft document request attached as an exhibit to Plaintiffs' Opposition to the Motion to Dismiss. The request is

[Footnote is continued on next page]

Even if this Court concludes that, on a 12(b)(6) motion, Plaintiffs can assert that an "avalanche of causal results" plausibly flows from baseless litigations (Tr. at 51), Defendants doubt they can maintain that pose on summary judgment. Confining the burden of discovery to these issues will aid the swift and economical resolution of this case.

III. THE GENERICS ARE NOT NECESSARY PARTIES

At oral argument, the Court noted the relationship between this case and Defendants' infringement cases against the four generic ANDA applicants, and asked for briefing on whether the ANDA applicants are indispensable parties to this litigation. We conclude that they are not necessary parties under Fed. R. Civ P. 19.

Fed. R. Civ. P. 19(a)(2) provides for joinder where

> a person claims an interest relating to the subject of the action and is so situated that the disposition of the action in the person's absence may (i) as a practical matter impair or impede the person's ability to protect that interest or (ii) leave any of the persons already parties subject to a substantial risk of incurring double, multiple, or otherwise inconsistent obligations by reason of the claimed interest.

Joinder of the generics is not appropriate or necessary under either subsection.

Rule 19(a)(2)(i) asks whether disposition of this case without joining the generic manufacturers might "impair or impede" their "ability to protect" their interests. The rights of the generic companies would not be adversely affected if the Court were to

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[Footnote continued from previous page]

quite broad, including asking for "all documents related to Wellbutrin" and "all documents related to Zyban."

conclude that Defendants' patent suits are constitutionally protected petitioning activity. This Court can simply conclude that each patent case raised issues on which there was a realistic chance for GSK to succeed on the merits. The Court will not need to rule that GSK's position is correct. See Prof'l Real Estate Investors, Inc. v. Columbia Picture Indus., Inc., 508 U.S. 49, 60 (1993).

Such a ruling will not impair the interests of the generics to the extent required for them to be necessary parties. The Third Circuit has held that only a direct threat of collateral estoppel should automatically trigger subpart (i) of Rule 19. See Janney Montgomery Scott, Inc. v. Shepard Niles, Inc., 11 F.3d 399, 406-08 (3d Cir. 1993). At argument, the Court recognized that collateral estoppel would not apply here. (Tr. at 8); see also Seborowski v. Pittsburgh Press Co., 188 F.3d 163, 169 (3d Cir. 1999) (holding that in order for estoppel to apply, "the party against whom the doctrine is asserted must have been a party or in privity with a party to the prior adjudication and have had a full and fair opportunity to litigate the issue in question in the prior action").

The Court may be concerned that its rulings will affect the rights of the generics to prosecute their own antitrust claims against Defendants. All of the generics have been aware of this case for months, however, and none of them has sought to intervene. Moreover, the only generics that raised antitrust counterclaims in the pending patent suits voluntarily dismissed them. Thus, based on their actions to date, none of the generics has displayed an interest in actively pursuing the types of claims asserted here.

Subsection (ii) of Rule 19(a)(2) likewise does not call for joinder of the generics. That section calls for joinder of nonparties where joinder will protect existing parties from "the substantial risk of incurring double, multiple, or otherwise inconsistent

obligations by reason of the [non-party's] claimed interest." While the injunctive relief that Plaintiffs seek in this case may well subject Defendants to inconsistent obligations,[20] that is a risk that cannot be eliminated by joinder of the generics as parties to this antitrust suit.

[20] Plaintiffs' Complaint asks this Court to bar Defendants from commencing and maintaining any patent infringement actions against filers of ANDAs for generic Wellbutrin. (Compl. Prayer for Relief ¶¶ B, D.) Granting this request would mean, among other things, enjoining Defendants from proceeding with three fully briefed appeals pending in the Federal Circuit and from going to trial in the Southern District of New York. The injunction sought likely would subject Defendants to inconsistent obligations. The Federal Circuit and Southern District of New York courts have entered and likely will continue to enter orders requiring Defendants to submit briefs, conduct oral argument, attend pretrial conferences, and the like. An order from this Court barring Defendants from proceeding with those cases would require Defendants to violate these and other Federal Circuit and Southern District of New York orders. Defendants believe there is ample ground to dismiss the Complaint for the reasons stated herein. Should the Court deny the Motion to Dismiss, we reserve the right to raise the issue in a later motion that the federal injunctive relief requested cannot be granted.

IV. CONCLUSION

For the reasons stated herein, Plaintiffs' Complaint should be dismissed.

Respectfully submitted,

William J. Baer
Kenneth A. Letzler
Cathy Hoffman
Amy Ralph Mudge
June Im
H. Holden Brooks
Arnold & Porter
555 12th St., NW
Washington, DC 20004
(202) 942-5000

Mark S. Stewart
Leslie E. John
Ballard Spahr Andrews & Ingersoll, LLP
1735 Market Street, 51st Floor
Philadelphia, PA 19103-7599
(215) 864-8225

Timothy A. Thelen
Assistant General Counsel
GlaxoSmithKline
Five Moore Drive
Research Triangle Park, NC 27709
Telephone: (919) 483-1480
Facsimile: (919) 315-1044

Counsel for GLAXOSMITHKLINE PLC
and SMITHKLINE BEECHAM CORP.
d/b/a GLAXOSMITHKLINE, INC.

Dated: May 5, 2003

CERTIFICATE OF SERVICE

I certify that the foregoing Defendants' Supplemental Memorandum in Support of Motion to Dismiss was served on the counsel listed in the service list below by fax and overnight mail on May 5, 2003.

Mark S. Stewart

SERVICE LIST

Anthony J. Bolognese
BOLOGNESE & ASSOCIATES, LLC
1617 JFK Boulevard, Suite 650
Philadelphia, PA 19103

Telephone: (215) 814-6750
Facsimile: (215) 814-6764

Marc A. Topaz
Joseph H. Meltzer
SCHIFFRIN & BARROWAY, LLP
Three Bala Plaza East
Suite 400
Bala Cynwyd, PA 19004

Telephone: (610) 667-7706
Facsimile: (610) 667-7056

J. Douglas Richards
Michael M. Buchman
MILBERG WEISS BERSHAD
HYNES & LERACH, LLP
One Pennsylvania Plaza
New York, NY 10119

Telephone: (212) 594-5300
Facsimile: (212) 868-1229

Thomas M. Sobol
Jeniene Andrews-Matthews
HAGENS BERMAN, LLP
225 Franklin Street
Boston, MA 02107

Telephone: (617) 482-3700
Facsimile: (617) 482-3003

Christopher A. O'Hara
1301 5th Avenue, Suite 2900
Seattle, WA 98101

Telephone: (206) 623-7293
Facsimile: (206) 623-0594